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C O N F I D E N T I A L SECTION 01 OF 02 AMMAN 001193

SIPDIS

STATE PASS USAID FOR TOM OLIVER
DOC FOR 4520/ITA/MAC/ONE/COBERG
HHS FOR JANE COURY

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SUBJECT: AMBASSADOR DISCUSSES NEW FDA, PHRMA ISSUES WITH
HEALTH MINISTER

Classified By: Ambassador Edward W. Gnehm, reasons 1.5 (b,d)

11. (c) Summary: Jordanian Health Minister Dr. Walid Ma'ani explained his plans to create a Jordanian FDA in a meeting with the Ambassador February 23. The Ambassador and Ma'ani also discussed drug pricing and registration concerns voiced by local PhRMA member company representatives. Following the meeting, the Ambassador participated in a handover ceremony, wherein PhRMA gave computers to the Ministry to help streamline operations. End summary.

FDA PLANS

12. (sbu) Health Minister told the Ambassador during a February 23 meeting that the GOJ is finalizing plans to create a Food and Drug Administration (FDA) as a means to streamline the food and drug trade in Jordan and to boost Jordanian pharmaceutical exports, especially to the U.S. and Europe. Ma'ani said he passed draft legislation to the cabinet in mid-February, and hoped for passage of the legislation by the end of March. If all went well, Ma'ani said he hoped to have the new FDA fully functional by the end of May.

13. (sbu) To that end, Ma'ani said a state-of-the-art building including labs and office space was already being built to house the new agency, which would be devoted "90%" to pharmaceutical industry issues, with one small lab for food testing. Ultimately, Ma'ani said another office would be added to certify medical equipment. Ma'ani said the FDA would be a semi-autonomous regulatory agency, reporting directly to the cabinet instead of being subsumed under any one ministry. He noted, though, that the Health Minister would sit on a "board of directors" for the new agency.

14. (sbu) The Ambassador noted that we had passed on to HHS and FDA the Minister's letter requesting technical assistance from FDA. He said the Minister could count on the Embassy's support in moving forward with whatever decision HHS/FDA made with regard to increasing cooperation with the GOJ.

DRUG PRICING, REGISTRATION ISSUES

15. (c) The Ambassador raised concerns voiced to us by local reps of multinational pharmaceutical companies and the regional PhRMA office regarding their input into proposed changes in Jordan's drug pricing and policies and registration procedures. On pricing, the Ambassador noted that PhRMA companies had been left out of advisory committees that were developing new procedures to price new-to-market drugs. He recommended the Minister meet with these companies to hear their ideas, and urged him to include these companies in committees making new policies governing the pharmaceutical industry. He noted that the multinational companies would provide a valuable perspective, particularly to ensure that new pricing policies do not inadvertently result in reduced access to innovative drugs in Jordan. The Minister agreed to involve PhRMA member companies more closely in such decision-making, and said he would be happy to meet with them.

16. (c) On registrations, the Ambassador noted that another proposal coming out of the advisory committees to withhold registration in Jordan of new medicines for a year after FDA approval as a "precautionary measure" would be counterproductive. First, it would deny Jordanians expeditious access to cutting-edge life saving drugs. Second, it would damage Jordan's attempts to grow its medical tourism industry, as prospective patients would have to go elsewhere to obtain these treatments. The Minister agreed that any new registration policy should keep the interests of all actors in mind, and agreed to revisit the registration committees proposals.

PHRMA COMPUTER DONATION

17. (u) Following their private meeting, the Ambassador and the Minister participated in a handover ceremony wherein PhRMA donated 25 networked PC's to the Ministry's Drug Directorate. The computers, according to PhRMA regional

director Samir Mansour, should help the Ministry to reduce the time needed to register new drugs by creating an extensive database and by moving much of the registration process into electronic format. PhRMA is now identifying a software firm to work with the Ministry to develop the database and registration programs. In remarks during the ceremony, the Ambassador praised Jordan's strong commitment to IPR protection and welcomed PhRMA's continued support for Jordan's health sector.

COMMENT

18. (c) We understand HHS is preparing to respond favorably to Ma'ani's request for technical assistance. We will work with Washington agencies to develop a program to address the GOJ's needs in setting up an FDA structure and in certifying local pharmaceutical firms for export to the U.S. of generic drugs as appropriate. We would note, though, that use of '03 ESF for this program would require negotiating with the Planning Ministry, as '03 ESF has already been programmed.
GNEHM